K123134

a passion for innovation

510(k) Summary

FEB 0 1 2013

Owner's Name & Address:	LDR Spine USA 13785 Research Boulevard, Suite 200 Austin, TX 78750 Phone: (512) 344-3333 Fax: (512) 344-3350
Contact Person:	Bradley W. Strasser, RAC Regulatory Affairs Project Manager Phone: (512) 344-3395 Fax: (512) 795-8306 Email: brad.strasser@ldrspine.com
Date:	January 28, 2013
Review Panel:	Orthopedic
Common Name:	Pedicle Screw Spinal System
Classification:	III/II
Classification Name:	Pedicle Screw Spinal System (per CFR 888.3070)
Product Codes:	NKB (per 21 CFR 888.3070)- Orthosis, spinal pedicle fixation, for degenerative disc disease MNH (per CFR 888.3070)- Orthosis, Spondilolisthesis, Spinal Fixation MNI (per CFR 888.3070)- Orthosis, Spinal Pedicle Fixation KWP (per CFR 888.3050)- Orthosis, Spinal Interlaminal Fixation
Proprietary Name:	LDR Spine Easyspine Posterior Spinal System
Legally Marketed Predicate Device:	LDR Spine Easyspine Posterior Spinal System • K043094, cleared February 11, 2005 • K063794, cleared January 24, 2007 • K082592, cleared October 8, 2008 • K121103, cleared August 24, 2012 Synthes Spine Matrix System • K100952, cleared August 5, 2010 • K092929, cleared December 29, 2009

LDR
a passion for innovation

Device Description:

The Easyspine Spinal System is a side-loading posterior spinal pedicle fixation system consisting of various implant components. The 4.25 mm pedicle screws and curved rods represent a line extension to the previously cleared Easyspine Spinal System (K043094, K063794, and K082592). The subject devices are identical to their predicates with respect to general technological characteristics and intended use.

Indications for Use:

The Easyspine® Posterior Spinal System is a posterior, non-cervical pedicle and non-pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Non-Clinical Testing:

Non-clinical testing on the proposed Easyspine 4.25 mm pedicle screws included testing in Static and Dynamic Axial Compression and Static Torsion in accordance with (per ASTM F-1717) and Axial Gripping Capacity and Flexion-Extension Cantilever (per ASTM F-1798).

The results of this testing demonstrate that the performance of the proposed LDR Spine Easyspine implants, when compared with their legally marketed predicates, are substantially equivalent.

Conclusion:

The Easyspine Posterior Spinal System has demonstrated substantial equivalence to previously cleared devices with respect to its indications and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

LDR Spine USA
% Bradley W. Strasser, RAC
Regulatory Affairs Project Manger
13785 Research Boulevard, Suite 200
Austin, Texas 78750

Letter dated: February 1, 2013

Re: K123134
Trade/Device Name: Easyspine Posterior Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: October 1, 2012
Received: November 5, 2012

Dear Mr. Strasser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123134

Device Name: Easyspine Posterior Spinal System

Indications for Use:

The Easyspine® Posterior Spinal System is a posterior, non-cervical pedicle and non-pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123134